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PATENT COOPERATION TREATY

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PATENT SERVICES
10/509513
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PCT
WRITTEN OPINION
DATA ENTERED
(PCT Rule 66)

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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Date of mailing
(day/month/year) 08 OCT 2003

Applicant's or agent's file reference
WJP1337 5913

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International Application No.
PCT/AU03/00381

International Filing Date (day/month/year)
28 March 2003

Priority Date (day/month/year)
28 March 2002

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ A61K38/45, 38/48 A61P 35/00

Applicant

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANIZATION et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:
28 July 2004
4. The applicant is hereby invited to reply to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. **If no response is filed by 1 month before the Final Date**, the international preliminary examination report will be established on the basis of this opinion. Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least **3 months before the Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6.

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I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 12-29	YES
	Claims 1-11	NO
Inventive step (IS)	Claims -	YES
	Claims 1-29	NO
Industrial applicability (IA)	Claims 1-29	YES
	Claims -	NO

2. Citations and explanations

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1) AU-A-27868/00	D5) US-A-5906922
D2) Lu, Yi	D6) US-A-5854224
D3) Secrist J et al	D7) Voeks, D et al
D4) Anderson, L et al	

New Citation

D8) Hofmann, C et al, J. Virology (1999) Vol. 73 No. 8 pages 6930-6936: 'Ovine Adenovirus Vectors Overcome Preexisting Humoral Immunity against Human Adenovirus In Vivo'. This document came to my attention during the search for another application. I apologise for any inconvenience that raising a new citation at this stage may have caused.

Novelty (N) Claims 1-11

D1 discloses engineered ovine adenoviruses (OAdV) as presently described, exemplified and claimed (for example see pages 12, 23, 24, Figure 12 and claims). The use of these constructs for the treatment of prostate cancer is clearly disclosed (pages 4, 8, 23 and claims). Therefore claims 1-11 lack novelty in light of D1.

D7 discloses the engineered ovine adenovirus OAdV220 as presently described, exemplified and claimed (for example, see Abstract). At the time of this report, the publication date of D7 was not available. If D7 were published after the priority date, this objection would be irrelevant. Therefore claims 1-11 lack novelty in light of D7.

Inventive Step (IS) Claims 1-29

D8 discloses the advantages of using ovine adenovirus (OAdV) as opposed to adenoviruses as vectors in gene therapy.

Each of D2, D3 and D4 discloses the use of gene directed enzyme prodrug therapy (GDEPT) using the same enzymes and prodrugs in the treatment of cancers, including prostate. The disclosed vectors include adenoviruses and adeno-associated viruses. It is considered that D2, D3 and D4, alone or in combination, with D1 or D8 deprive claims 1-11 of inventive step.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D5 and D6 each disclose the use of the presently defined lipids as facilitating the transfer of DNA into cells. The Applicant describes lipids as known to enhance the transfer of DNA into cells and to enhance the immune response (page 10). Thus it is considered that D5 and/or D6 in combination with D1 deprive(s) claims 12-29 of inventive step

Industrial Applicability (IA) Claims 1-29

Claims 1-29 are considered to be industrially applicable.